DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC - 1 2011

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER

James R. Overman, N.D.
Owner
Precision Herbs, LLC
9804 Township Road 89
Killbuck, OH 44637

Dear Dr. Overman:

The Food and Drug Administration (FDA) has learned that your firm is marketing the following products in the United States (U.S.) without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act):

1. Chi Max Protectors
2. Chi Max Water Wand
3. Chi Modulator Attachment
4. Electrolysis Foot Tub
5. Harmonic Combo
6. Harmonic Quad HQ5
7. Harmonic Transmitter
8. Healing Detox Attachment
9. Heart-Shaped Pocket Diode
10. Reflective Blanket

The Office of Compliance, in the Center for Devices and Radiological Health (CDRH) reviewed your firm's website, www.precisionherbs.com, for the aforementioned products. Under section 201(h) of the Act, 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

These devices are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). The devices are also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the agency. [21 CFR 807.81(b)] The kind of information that your firm needs to submit in order to obtain approval or

clearance for the devices is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate the information that your firm submits and decide whether the products may be legally marketed.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date your firm receives this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to: H. Charles Cathlin Jr. at the Food and Drug Administration, 10903 New Hampshire Avenue, WO66-2648, Silver Spring, MD 20993, or via facsimile to (301)847-8128. Refer to the Unique Identification Number CMS case # 229574 when replying.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,

Steven D. Silverman
Director
Office of Compliance
Center for Devices and Radiological Health